K090762

Section 5

AUG 28 2009

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date 04-10-08 [21 CFR 807.92(a)(1)].

A. Contact Information [21 CFR 807.92(a)(1)]

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Contact person: Dr. Dietmar Fischer, Director R&D

B. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: LEDA

Device Common Name: Light-based Therapy Device for Dermatology

Classification Name: Laser Instrument, Surgical Powered (per 21 CFR 878.4810)

Product Code: GEX

Panel: Dermatology and Plastic Surgery

Device Classification: Class II

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C. **Predicate Devices** [21 CFR 807.92(a)(3)]

The LEDA device uses similar technology and has equivalent physical output characteristics as the following predicate devices:

- For LEDA applicator SCR 585 yellow:
  - GentleWaves LED Light Photomodulation Device (K031425) manufactured by BioScience L.L.C.

- For LEDA applicator SCR 635 red:
  - Omnilux Revive (K030426) manufactured by Photo Therapeutics Inc.
  - VersaClear (K051259) manufactured by TheraLight Inc.

Summary: The LEDA LED applicators, SCR 585 yellow and SCR 635 red, are technically nearly identical ith the predicated devices. They all use LED technology and the physical output parameters (selectable power and dose) are nearly identical.

Power range: 4 mW/cm^2 up to 120 mW/cm^2.

Dose range: 0.1 J/cm^2 up to 100 J/cm^2.

- For LEDA applicators EPI 808 and EPI 980:
  - LightSheer (K973324, K982940, K001746) manufactured by Lumenis (formerly Star Medical / Coherent Star)
  - Quanta System's Diode Medical Laser Family (K072034) manufactured by Quanta System SpA
  - MYDON (K040384) manufactured by Quantel Derma GmbH (formerly Wavelight)

Summary: The LEDA LED applicators EPI 808 and EPI 980 use laser diode technology. Predicated devices are LightSheer (for 808 nm) and the Quanta System's Diode Medical Laser Family (for 808 nm and 980 nm). The device MYDON (a solid state laser) is an additional predicate for the LEDA EPI 980. The medical effect of a hair removal laser depends on the fluence and pulse duration. The technological differences do not raise new types of safety and efficacy issues because physical output parameters of all devices are absolutely comparable.

Fluence range: 6 – 60 J/cm^2 (LEDA EPI 808)

9 – 90 J/cm^2 (LEDA EPI 980)

15 – 100 J/cm^2 (MYDON)

10 – 60 J/cm^2 (LightSheer)

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Pulse duration range: 6 – 60 ms (LEDA EPI 808 and EPI 980)
10 – 90 ms (MYDON)
5 – 100 ms (LightSheer)

D. Device Description [21 CFR 807.92(a)(4)]

The system is composed of a table-top base unit that includes the power supply, software and cooling system. Different applicators containing the light sources can be plugged into the base unit. The device is controlled by a touch-screen graphic user interface. There are three kinds of applicators each of which is available with several wavelengths. For details see the following section.

The *LEDA* is a device designed for dermatological use. Depending on the applicator selected wavelength in the range of 550-1,000 nm are produced either by Light Emitting Diodes (LED) or Diode Lasers. For each applicator and thus each wavelength there is a specific set of medical indications.

E. Device Specifications [21 CFR 807.92(a)(6)]

The LEDA emits light of different wavelength depending on the selected applicator. Depending on the applicator a subset of the following parameters can be adjusted by the user: pulse duration, power density, fluence, repetition rate, irradiation dose, pause between irradiations and pulse on / off times.

There are two different kinds of applicators:

- SCR applicators: These are screen (SCR) applicators with LED light sources that are mounted on a holder. The patient is placed 14 cm in front of the screen without direct contact to the device. An area of about 16 cm times 10 cm is irradiated. SCR applicators are available with the wavelengths 635 nm (red) and 585 nm (yellow). The user selects dose, power density, and pulse on / off times. After pressing the start button on the display of the base unit irradiation starts until the entered dose is reached or the user switches off the radiation.

- EPI applicators: These are handheld applicators intended for epilation (EPI) treatments. They contain a diode laser light source and a scanner that moves the treatment spot over skin. EPI applicators are available with wavelengths 808 nm or 980 nm. The

scanned area is 1.2 cm times 5.0 cm and can be reduced to 1.2 cm times 1.2 cm by another distance holder. The user selects fluence, pulse duration, and pause between scans. When pressing a foot switch the scanning starts until the whole area has been scanned or the user releases the foot switch.

F. Indications for Use [21 CFR 807.92(a)(5)]

510(k) Number (if known): K090762

Device Name: LEDA

Indications for Use:

The *LEDA* System with the Applicator LEDA SCR 585 yellow is indicated for the treatment of periorbital wrinkles and rhytides.

The *LEDA* System with the Applicator LEDA SCR 635 red is indicated for the treatment of superficial, benign vascular and pigmented lesions.

The *LEDA* System with the Applicators LEDA EPI 808 and LEDA EPI 980 is indicated for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime.

G. Conclusion [21 CFR 807.92(b)(3)]

Technologically, the LEDA was found to be substantially equivalent to the following the currently cleared devices depending on the LEDA applicator:

- For LEDA applicator SCR 585 yellow:
  - GentleWaves LED Light Photomodulation Device (K031425) manufactured by BioScience L.L.C.
- For LEDA applicator SCR 635 red:
  - Omnilux Revive (K030426) manufactured by Photo Therapeutics Inc.
  - VersaClear (K051259) manufactured by TheraLight Inc.
- For LEDA applicators EPI 808 and EPI 980:
  - LightSheer (K973324, K982940, K001746) manufactured by Lumenis (formerly Star Medical / Coherent Star)

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- Quanta System's Diode Medical Laser Family (K072034) manufactured by Quanta System SpA
- MYDON (K040384) manufactured by Quantel Derma GmbH (formerly Wavelight)

Thus, the risks and benefits for the LEDA are comparable to the predicate devices.

The indications for use are exactly the same as the previously cleared systems which are listed above.

We believe that there are no new questions of safety or efficacy raised by the introduction of the *LEDA*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Silver Spring, MD 20993-0002

Quantel Derma GmbH
% Underwriters Laboratories, Inc.
Mr. Casey Conry
1285 Walt Whitman Road
Melville, New York 11747

AUG 2 8 2009

Re: K090762
Trade/Device Name: LEDA
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ONF
Dated: August 7, 2009
Received: August 11, 2009

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K090762

Device Name: LEDA

Indications for Use:

The *LEDA* System with the Applicator LEDA SCR 585 yellow is indicated for the treatment of periorbital wrinkles and rhytides.

The *LEDA* System with the Applicator LEDA SCR 635 red is indicated for the treatment of superficial, benign vascular, and pigmented lesions.

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden Sorman

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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